(21)

Supreme Court, U.S.
FILED
JUL 16 2001
OFFICE OF THE CLERK

No. 99-1996

In The

Supreme Court of the United States

J.E.M. AG SUPPLY, INC. (doing business as Farm Advantage, Inc.), FARM ADVANTAGE, INC., LARRY BENZ, MERLE PRUETT (doing business as Siouxland Seeds, Inc.), KEVIN WOLFSWINKEL, TIM KAMSTRA, and TOM EISCHEN SEED & CHEMICALS,

Petitioners,

v.

PIONEER HI-BRED INTERNATIONAL, INC.,

Respondent.

On Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit

REPLY BRIEF FOR PETITIONERS

BRUCE E. JOHNSON
(Counsel of Record)

S. P. DEVOLDER

LEWIS, WEBSTER, JOHNSON,
VAN WINKLE & DEVOLDER, L.L.P.
418 Sixth Avenue
Liberty Building, Suite 620
Des Moines, Iowa 50309-2407
Telephone (515) 243-1000
Facsimile (515) 288-7000
Attorneys for Petitioners

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
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ARGUMENT

I. UTILITY PATENTS ISSUED ON SEXUALLY REPRODUCING PLANT VARIETIES, THE PARTS THEREOF AND THEIR SEEDS ARE INVALID AND CANNOT CONFER THE RIGHT TO EXCLUDE OTHERS FROM SEXUALLY REPRODUCING PLANT VARIETIES, OR FROM SELLING OR USING PLANT VARIETIES REPRODUCED SEXUALLY, BECAUSE THESE VARIETIES AND SEEDS ARE SUBJECT TO FEDERAL PROTECTION ONLY THROUGH THE ISSUANCE OF CERTIFICATES OF PLANT VARIETY PROTECTION.

A. Pioneer And Its Amici Misapprehend The Statutes And Farm Advantage's Position When They Argue Farm Advantage Relies On An "Implicit Repeal."

Pioneer and its amici assert that Farm Advantage's statutory construction argument is premised on an "implicit repeal"; specifically, that the enactment of the 1970 PVPA effected by implication a narrowing of the coverage of 35 U.S.C. § 101. Pioneer brief, at 4-5, 18, 26, 28 and 34-36.[1] This is a mischaracterization of Farm Advantage's position. Pioneer and its amici's response further is based on an absolute misunderstanding of the successively enacted plant-specific statutes.

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[1] Most of the amici repeat Pioneer's argument. AILP, at 2; ABA, at 5-8; Cargill, at 6-9; WLF, at 5-9. Rule 37 provides that an "*amicus curiae* brief [that does not bring to the attention of the Court relevant matter not brought to its attention by the parties] . . . burdens the Court, and its filing is not favored." Pioneer's amici briefs, submitted by seed producers and their trade organizations, amount to repetitions of the same arguments put forth by Pioneer and the Solicitor General.

Pioneer misstates the statutory history when it says the only change to § 101 and its precursors since 1793 was the substitution of the word "process" for "art." Pioneer, at 5 and 26. This is not true. The 1930 PPA was a direct amendment to the utility patent provisions, including the subject matter provision then contained in Revised Statutes § 4886 (the direct precursor of § 101). The PPA placed in § 4886 a new category of things subject to utility patent protection, "plants," but limited to those plants reproduced by asexual methods. The PPA amendment to § 4886, and to the other utility patent provisions, *expressly* excluded from patent protection a plant's seeds and any plants reproduced by sexual methods. Revised Statutes, §§ 4884, 4886 and 4888. Section 4886, after the 1930 PPA, remained unchanged until the 1952 reenactment of the Patent Act.

The second *express* change to the utility patent subject matter provision occurred during the 1952 reenactment. Congress removed the term "plants" from § 101 and placed it into the newly enacted § 161, retaining the existing asexual reproduction limitation. This change in § 101 was described in Senate Report No. 82-1979, which provides (1952 WL 3180, p. 10): "Section 101 follows the wording of the existing statute [*i.e.*, Revised Statutes § 4886] as to the subject matter for patents, except that reference to plant patents has been omitted for incorporation in section 301 [35 U.S.C. § 161]. . . . "

The 1930 PPA and the 1952 reenactment resulted in express changes to § 101 (and its precursor) that directly involved the subject of the patentability of plants. In 1930, the new patentable category of "plants" was added, but limited to those plants reproduced by asexual

methods. Had Congress also wanted plants that are propagated by sexual methods to be patentable subject matter, then it would not have imposed the express asexual reproduction limitation. In 1952, Congress removed from § 101 the entire category of "plants" and placed that category into a separate chapter ("Patents for Plants") with the retention of the asexual reproduction limitation. These statutory enactments are express limitations on § 101; they are not limitations by implication.

The PVPA was enacted in 1970, following years of debate on whether Chapter 15 of Title 35 ("Patents for Plants") should be amended to provide patent protection for plants propagated by sexual methods. Patent Law Revision Hearings, Subcommittee on Patents, Trademarks and Copyrights, Senate Judiciary Committee, 90th Cong., 2nd Sess., 1968, Part 3. Rather than constitute an "implicit repeal," the 1970 PVPA was a deliberate decision on Congress' part not to sanction the granting of patent protection for seed grown plants. S.R. No. 91-1246, at pages 2-3 (quoted at pages 40-41 of Farm Advantage's principal brief).

Some of Pioneer's amici take Pioneer's statutory construction argument one step further. They assert that, if the 1970 PVPA was enacted by Congress in express recognition that seed grown plants were not patentable, then the Court's *Chakrabarty* decision and the PTO's *Hibberd* opinion prove that the 1970 Congress acted on a mistaken belief – the product of nature/living things doctrine. ABA, at 11; WLF, at 5; BIO, at 5, n. 3. These amici argue the judiciary and PTO are not bound by the 1970 Congress' interpretation of § 101 as that interpretation was mistaken.

There are three obvious rejoinders to this argument. First, as early as 1930, Congress recognized plants, despite being "living things," could be subject to patent protection. Congress determined in the PPA to limit patent protection to plants that are reproduced asexually. Congress did not base this decision on the product of nature/living things doctrine, but on its conclusion patent protection was undesirable when applied to sexual reproduction of plants. Second, from 1965-70, Congress and a presidential commission considered whether the plant patent provisions should be amended to permit the patenting of seed grown plants. Ultimately, different but patent-like protection was provided through the 1970 PVPA, that like the 1930 PPA accords federal protection to a "living thing" (the right to exclude others from reproducing plants by seed). A separate act was enacted not based on the product of nature-living things doctrine, but rather to ensure that the historic rights of plant breeders to experiment with another's seed and of farmers to save seed were protected, that a specialized agency would administer the federal protection, and that other aspects of the seed grown crops industry would not be changed by application of federal law. 7 U.S.C. §§ 2321, 2323, 2327, 2541(d) and 2543-44. Third, even if Congress was "mistaken" (which it was not), the amici's argument goes nowhere. The fact is Congress *legislated* on the precise subject in 1930, 1952 and 1970. The judiciary cannot nullify legislation on the basis of Congress' motivation in legislating. Acceptance of the amici's argument would permit federal courts to overrule legislation whenever

they deemed some member(s) of Congress voted for legislation when mistaken, uninterested or otherwise confused.

B. *Chakrabarty* Supports Farm Advantage And The *Hibberd* Decision Has No Claim To Judicial Deference.

Pioneer and its amici rely on an incorrect characterization of *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). They argue, to the effect, that the *Chakrabarty* Court settled the question of whether § 101 covers the reproduction (sexual and asexual) of plants. Pioneer, at 34-38; AIPL, at 3; Cargill, at 4-6; BIO, at 16-17; ASTA, at 7-9. The Solicitor General's brief typifies the argument, and Farm Advantage addresses it.

The Solicitor states "[t]he *Chakrabarty* Court then rejected the argument that Congress's enactment of the PPA and the PVPA reflected an understanding that plants could never be patented under Section 101." U.S., at 11. From this premise, the Solicitor ultimately concludes the *Chakrabarty* Court actually held plants were included within § 101 and that the PTO board in *Ex Parte Hibberd*, 227 U.S.P.Q. 443 (Bd. Pat. App. & Interf. 1985), simply applied this straightforward holding. U.S., at 11-17. The Solicitor maintains Farm Advantage can only prevail if the Court overrules *Chakrabarty*. U.S., at 11-17.

Like respondent and its amici's statutory construction argument, this case law argument is grounded on a faulty first premise. The petitioner in *Chakrabarty* argued the enactments of the PPA and PVPA showed Congress' intent that *no* living thing was patentable subject matter.

Chakrabarty, 447 U.S. 310-11 and 314. The four dissenting Justices agreed. *Id.*, at 318-22 (Brennan, J., dissenting). The *Chakrabarty* majority countered that the enactment of the plant-specific statutes could not be taken as conclusive evidence of Congressional intent that § 101 could never encompass *any* living thing such as a micro-organism modified or created by genetic engineering. *Id.*, at 311-14. The majority agreed with the dissent that, with respect to "plants," Congress did express its intent to exclude this form of living thing from § 101's terms "manufacture" or "composition of matter." *Id.*, at 318. The majority instructed that Congress can exclude a living thing from § 101 by "craft[ing] a statute specifically designed for such living things." *Ibid.* The majority here was endorsing the limitation on the "anything under the sun" statement that Judge Rich acknowledged in *Application of Bergy*, 596 F.2d 952, 987 n. 25 (Cust. & Pat. App. 1979), *affd. sub nom., Diamond v. Chakrabarty*, 447 U.S. 303 (1980): "We recognize that, at the time the statement was made, its authors realized that Congress did not intend the term 'manufacture' in § 101 to include plants, which were specifically provided for elsewhere."

Far from being a direct application of *Chakrabarty*, the PTO board's *Hibberd* ruling contravenes the *Chakrabarty* analysis as well as the Court's discussion of the plant-specific statutes and their purpose in *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179 (1995). The PTO issued its notice that it "is now examining applications including claims to plant life – e.g., plants per se, seed, plant parts" in response to the board's *Hibberd* ruling. 1060 O.G. 4 (Oct. 8, 1985). That ruling was not based on the PTO's rulemaking process following a period of notice-and-comment.

The ruling is not entitled to judicial deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), and accordingly *Hibberd* must stand on its own persuasive force without any entitlement to deference. *United States v. Mead Corp.*, ___ U.S. ___, 121 S.Ct. 2164, 2168 and 2172-75 (2001).[2] The *Hibberd* ruling has no persuasive power for the reasons stated in Farm Advantage's principal brief.

C. A Miscellaneous Provision Buried In The American Inventors Protection Act Of 1999, Which Itself Was Passed As A Small Part Of A Voluminous Consolidated Appropriations Act, Is Not Evidence Of Congressional Intent To Sanction The Patentability Of Plants Under § 101.

Pioneer argues 35 U.S.C. § 119(f), a miscellaneous provision of the American Inventors Protection Act of

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[2] Amicus United States at 17 cites *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723 (1975), and *Blau v. Lehman*, 368 U.S. 403 (1962), in support of a contention that Congressional failure to legislate against the PTO's practice is an endorsement of that practice. In *Blue Chip*, the Securities and Exchange Commission had unsuccessfully sought to persuade Congress to overrule a long-standing Court of Appeals decision, not an agency practice. In *Blau*, Congress had also refused to legislate to change a Court of Appeals interpretation of § 16(b) of the 1934 Securities Exchange Act and rejected the SEC's attempt to do so. The Court said: "Congress can and might amend § 16(b) if the Commission would present to it the policy arguments it has presented to us, but we think that Congress is the proper agency to change an interpretation of the Act unbroken since its passage, if the change is to be made." 368 U.S. at 413.

1999, evidences Congress' intent that plants (both sexually and asexually propagated) are patentable subject matter under § 101. Pioneer, at 41-46. Pioneer's argument is not supported by the terms of § 119(f) and the 1999 Act's history.[3]

Section 119(f) does not purport to address the issue of whether the terms "manufacture" and "composition of matter" appearing in § 101 should be construed to include "plants." Subsection (f) simply is part of a general provision, § 119, that provides for priority filing in the U.S. for an inventor who filed for patent protection in a foreign country within the preceding twelve months. 35 U.S.C. § 119(a). The Patents for Plants chapter of the patent act, 35 U.S.C. §§ 161-64, includes § 119(f) because the general patent provisions are incorporated into the plant patents chapter. 35 U.S.C. § 161 ("The provisions of this title relating to patents for inventions [utility patents] shall apply to patents for plants, except as otherwise provided."). Thus, it is not surprising that § 119's priority filing would be written in subsection (f) to apply to plants.

Section 119 is part of the "miscellaneous patent provisions" contained in the American Inventors Protection Act of 1999. H.R. 1907, appearing in Congressional Record (August 3, 1999), at H6929-H9650. The Act comprised 105 pages of text. *Id.*, at H6945 (statement of Ms. Kaptur). The Act was submitted under a manager's amendment that suspended the normal rules of debate.

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[3] In case the reader managed to miss Pioneer's argument the first time around, it is dutifully repeated by the amici. U.S., at 19-21; ABA, at 10-13; BASF, at 4-10; and BIO, at 21-22.

H6941 and H6945. It was "debated" for 20 minutes late in the evening on the day before it was scheduled for full House vote, and ultimately was passed as part of a massive year-end omnibus revenue bill. Pub.L. 106-113, Nov. 29, 1999, Consolidated Appropriations Act of 2000. The miscellaneous provisions of the Act, including § 119(f), were not discussed during the 20 minutes of debate. H6929 – H6950.[4] H.R. 1907 was reopened as unfinished business at 11:02 a.m. and passed without further debate at 11:12 a.m., August 4, 1999. Library of Congress Thomas Service, *Bill Status 106th Cong.*, <http://thomas.loc.gov/bss>. Two House members who were allowed to share ten minutes of the truncated debate had these observations:

> Therefore, when a 105-page bill comes before us on suspension, those of us who value this document [the Constitution] and devote much of our lives to preserving it under the oath that we take are very suspicious of any bill of such consequence that comes before us on suspension when we are allowed only 10 minutes to debate.

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[4] Pioneer at 44-45 quotes from page 328 (actually 145-46) of the House Conf. Rep. (106-464) to the Intellectual Property and Communications Omnibus Reform Act of 1999, Nov. 9, 1999, a reference to "utility patent protection for a plant variety." This reference was contained at page 68 of the 160 page House Report, 106-287, to accompany H.R. 1907, the American Inventors Protection Act of 1999, August 3, 1999. That August 3, 1999, evening Representative Kaptur said with regard to the actual statutory text, at H6945:

> There is a manager's amendment now which was walked to the floor at 9:17 p.m., which I could only get up to Page 54 reading very quickly here this evening. There are 105 pages in the bill.

> I would also say that with all due respect to the excellent minds that were involved in crafting this manager's amendment, it is only a handful of Members of this institution. This bill is not up on the web. I cannot ask the inventors I represent back home to go to any site to look at it so I can be advised on how to vote tomorrow morning.
>
> I know a fast ball when I see one. I have been here long enough to know that. I am offended by this, simply because I think the constitutional issues are so very important. * * *

H6945 (statement of Ms. Kaptur).

> We have now had changes in the bill which the gentlewoman from Ohio (Ms. Kaptur) has referred to which, frankly, I have not had the opportunity to review fully, and I have a sense that maybe I am with the 430 people in this House. There perhaps have been four or five who have reviewed this legislation. But I am very concerned that we are moving this tonight on suspension.

H6946 (statement of Mr. Hoyer).

Section 119(f) was not debated by Congress for the specific purpose to approve the issuance of utility patents on plants. The legislative history cited by Pioneer and its amici amount to sparse statements, mostly by seed producing industry members, of the historical fact that since *Hibberd* the PTO has issued utility patents on plants. The statements are not directed toward § 119(f) in particular and the view that its enactment will result in Congress' explicit (or even implicit) approval of the PTO's practice.

The isolated statements, contained in volumes of legislative reports, do not show Congress considered the precise issue at hand. These few references are in stark contrast to Congress' attention to this issue prior to passing the 1930 PPA and Congress' extensive consideration of the precise issue during the 1965-70 hearings that culminated with the passage of the PVPA. Congress has rejected extending Title 35 to cover seed grown plants on *every occasion* it has considered the precise issue.

Section 119(f), which does not mention § 101, and isolated statements by seed industry advocates that utility patents on seed grown plants have been issued by the PTO since the agency's *Hibberd* ruling do not equate to Congressional awareness that this agency practice exists, let alone Congressional intent to sanction this practice. In *Securities and Exchange Comm'n. v. Sloan*, 436 U.S. 103, 121 (1978), the Court observed:

> We are extremely hesitant to presume general congressional awareness of the Commission's construction based only upon a few isolated statements in the thousands of pages of legislative documents. That language in a Committee Report, without additional indication of more widespread congressional awareness, is simply not sufficient to invoke the presumption in a case such as this. For here its invocation would result in a construction of the statute which not only is at odds with the language of the section in question and the pattern of the statute taken as a whole, but also is extremely far reaching in terms of the virtually untrammeled and unreviewable power it would vest in a regulatory agency.

See also Whitman v. American Trucking Associations, Inc., 531 U.S. 457, 121 S.Ct. 903, 909-10 (2001) ("Congress, we have held, does not alter the fundamentals of a regulatory scheme in vague terms or ancillary provisions – it does not, one might say, hide elephants in mouseholes."); *Sorenson v. Secretary of Treasury of U.S.*, 475 U.S. 851, 867 (1986) (Stevens, J., dissenting) ("I think 'it defies belief' to assume that a substantial number of legislators were sufficiently familiar with [Omnibus Budget Reconciliation Act of 1981] to realize that somewhere in that vast piece of hurriedly enacted legislation there was a provision that changed the 6-year-old Earned Income Credit Program.").

D. The PVPA Requires Disclosure, Including A Seed Deposit, And Under The Research Exemption Discloses To Others The Plant Variety's DNA Storehouse Of Information, Whereas Patent Law Precludes Others From Exploring Through Research The DNA Information Of A Plant Variety Whose Sexual Reproduction Is Claimed To Be Controlled By A Utility Patent.

Pioneer, again parrotted by its amici, argues that a plant breeder who seeks a § 101 utility patent to legally monopolize the act of propagating a seed grown plant must meet two different (and supposedly more difficult) requirements than the breeder who seeks a PVP certificate to monopolize the same act – a complete written description of the plant and a showing that the plant is "non-obvious." Pioneer, at 38; U.S., at 24-25; Cargill, at 16; ACPA, at 5-6; BIO, at 6-8; ASTA, at 6, 14-15. This argument fails for both legal and factual reasons.

First, the argument has no legal relevance even if it is factually true (which it is not). It has been shown that Congress directly considered, in 1930, 1952 and 1965-70, whether Title 35 patents should be available to protect seed grown plants. In 1930, Congress deliberated on whether to extend the Revised Statutes § 4886 (precursor of § 101) new protection of "plants" to the right to exclude sexual reproduction, and in 1965-70 whether to extend the protection afforded by plant patents (35 U.S.C. §§ 161-64) to the right to exclude others from propagating plants by sexual methods. In the end, Congress determined not to extend Title 35 patent rights to include the right to exclude sexual reproduction of seed grown plant varieties. Instead, it enacted a separate statutory scheme, the 1970 PVPA. Of course, Congress did not make that scheme identical to the utility or plant patent provisions of Title 35. Had it wished to do so, then it would have amended these provisions, as it did with the 1930 PPA, instead of enacting a separate statute. Nowhere in the briefs of Pioneer and its amici do they point to a deliberate Congressional decision that standards different than the PVPA standards may be used to grant the right to exclude sexual reproduction, that the research exception can be avoided, or that the seed saving exemption can be circumvented.[5] The differences in the statutes,

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[5] When the 1994 PVPA Amendments removed from 7 U.S.C. § 2543 the right of a farmer to sell saved seed, the House Report (Agricultural Committee) No. 103-699, Aug. 12, 1994 (To Accompany H.R. 2927), provided in Section 10, p. 17:

> It is not the intent of the Committee that deletion of the provision allowing the sale of saved seed to be viewed as a step toward the eventual end to the

summarized by Farm Advantage at pages 22-24 of its principal brief, prove Farm Advantage's position. The statutes in fact conflict and seed grown plants, the parts thereof and their seeds are subject to federal protection only under the PVPA.

Pioneer and its amici in any case base their argument on incorrect facts. The utility patent disclosure provision, 35 U.S.C. § 112, requires a complete written description of the patented invention. Congress relaxed this description requirement only in the case of plant patents. 35 U.S.C. § 162. Congress has not relaxed the written description requirement for an invention protected by a § 101 utility patent. It is the PTO, not Congress, that endorsed the substitution of a seed deposit for a written description to satisfy by proxy the written description requirement of § 112. Note that Pioneer's patents on the corn hybrids contain *no* disclosure of the hybrid's DNA in the written description (J.A., 31-32), and only a partial gene disclosure for its patents on the corn inbreds (J.A., 45). For Pioneer's corn hybrid patents, the PTO did not require a deposit of the hybrid's inbred parents or even require identification of the inbred parents and their breeding history. Pioneer's corn inbred patents also do not disclose their breeding history – i.e., how they were made.

For both its patented hybrid and inbred corn varieties, Pioneer purports to meet § 112's written description requirement by the deposit of seeds. (J.A., 39, 50.) Yet patent law prohibits another from experimenting on the

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traditional right of farmers to save seed for use on their own holdings. * * *

patented invention, and consequently one skilled in the art of plant breeding cannot recreate the patented plants simply from the existence of a seed deposit.[6] For example, a researcher is precluded by patent law from growing the deposited seeds and experimenting on the resulting plants by observing them and by cross-pollinating them with other plant varieties to study the results of this DNA interaction.

The PTO in essence has administratively amended the disclosure requirement of § 112 to make it somewhat follow the disclosure provision of the PVPA. That provision requires a written description that describes the protected plant variety in much the same manner that Pioneer's patented corn varieties are described in the patents-in-suit. 7 U.S.C. § 2422(2). Additionally, the PVPA requires a deposit of seeds from the protected variety. *Id.*, at § 2422(4); *see also* 7 C.F.R. § 97.6(d). The PVPA also requires that all known genealogy and breeding history be described in an application for plant variety protection. 7 U.S.C. § 2422(2). This crucial information is absent from the patents granted by the PTO to Pioneer. Pioneer and its amici's reliance on the written description requirement for utility patents in fact supports Farm Advantage's position.

Pioneer and its amici make another mistake of fact when they rely on the utility patent requirement of "non-obviousness." This requirement must be met by a breeder who seeks to patent an asexually propagated plant. 35

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[6] Amer. Crop Prot., 9-10; BIO, 11; U.S. 24, 25 n.12; *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 496 U.S. 856 (1984).

U.S.C. § 161. As it respects plants, "non-obviousness" equates with distinctiveness. The seed producing industry itself recognizes this. During the hearings on the Plant Variety Protection Act Amendments of 1993, the statement of the National Potato Council (H.R. 2927, at 95-104) provided (*id.*, at 101):

> A plant patent may be granted to anyone who invents or discovers and asexually reproduces a variety which is distinct, novel and non-obvious. In practice, the application of the criterion non-obviousness to plants seems to be linked to distinctiveness. For example, the candidate variety must be distinct by something more than a minor (cosmetic) characteristic.

The PVPA requires a breeder of a new variety of seed grown plant to show that the variety is "distinct." 7 U.S.C. § 2402(a)(2). The term "distinctiveness" in the PVPA is construed as follows:

> The distinctiveness of one variety from another may be based on one or more identifiable morphological, physiological, or other characteristics (including any characteristics evidenced by processing or product characteristics, such as milling and baking characteristics in the case of wheat) with respect to which a difference in genealogy may contribute evidence.

Id., at § 2401(b)(5). "Distinctiveness" is the PVPA's equivalent of the PPA's requirement of "non-obviousness." The requirements in practice are applied in a related and overlapping manner. Pioneer and its amici's reliance on this difference in wording as a factual matter is without substance.

E. The PVPA Includes Genetically Engineered Plants That Are Sexually Reproduced.

Amici Delta and Monsanto do raise an argument not put forth by Pioneer and the Solicitor General. It is that the term "variety" in the PVPA is not (necessarily) broad enough to cover all forms of sexually reproduced plants. The plants supposedly not included are those plant varieties that in part have been genetically engineered, and as contrasted with those plant varieties developed entirely by "classical" breeding techniques. Delta, at 4-14; Monsanto, at 4-7. These amici do not correctly characterize the PVPA's scope of coverage.

The word "variety" is defined in the PVPA as follows:

> The term "variety" means a plant grouping within a single botanical taxon of the lowest known rank, that, without regard to whether the conditions for plant variety protection are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one characteristic and considered as a unit with regard to the suitability of the plant grouping for being propagated unchanged. A variety may be represented by seed, transplants, plants, tubers, tissue culture plantlets, and other matter.

7 U.S.C. § 2401(a)(9). The term "variety" is expansive; it expressly includes all plant groupings that fall "within a single botanical taxon of the lowest known rank." *Ibid.*

Contrary to Delta and Monsanto's assertion, the term "variety" expressly includes a seed grown plant that is developed by genetic engineering instead of through utilization of "classical" plant breeding techniques. The PVPA's infringement provisions apply to "any variety that is essentially derived from a protected variety. . . . " 7 U.S.C. § 2541(c)(1) (added by 1994 PVPA Amendments, Pub.L. 103-349, § 9(3)). The PVPA provides that any plant variety falling within the definition of "essentially derived variety" set out in 7 U.S.C. § 2401(a)(3) is not exempted merely because it has been genetically engineered. *Id.*, at § 2401(a)(3)(B). This section provides:

> Methods
>
> An essentially derived variety may be obtained by the selection of a natural or induced mutant or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, *transformation by genetic engineering*, or other method. [Emphasis added.]

Ibid. The PVPA covers the field of federal protection for obtaining a PVP Certificate holder's right to exclude others from sexually or tuber propagating a plant variety, even a variety created through the use of biotechnology. *Id.*, at §§ 2401(a)(6), (7) (definitions of propagation) and 2541 (acts of infringement by propagation).

To be commercially valuable, a plant developed in some part by genetic engineering must be propagated by sexual, tuber or asexual methods, whichever is most appropriate for that particular variety of plant. The PVPA encompasses all aspects of plant propagation, with the exception of the PPA carve-out for asexual reproduction. 7 U.S.C. § 2541(a)(9). A plant variety having a genetically

engineered input, just like an entirely classically bred plant variety, must be propagated to be valuable. A plant that cannot be economically reproduced has no value in the commercial crop market. The plant varieties that have a genetic engineering input are developed through classical plant breeding either before or after the genetic engineering, or both before and after the engineering event. The plant varieties for which Delta and Monsanto claim patent rights to control or prohibit their sexual reproduction are propagated by sexual means, in the same manner the plant varieties covered by the patents-in-suit issued to Pioneer are propagated. The right to exclude others from sexually reproducing these plant varieties, like Pioneer's patented plants, are exclusively protectable by federal law under the PVPA for they are sexually propagated.

CONCLUSION

A breeder who has developed and sexually reproduced a plant variety cannot obtain under 35 U.S.C. § 101 a patent granting the right to exclude others from sexually reproducing the plant variety, or from selling or using plant varieties reproduced sexually. Such a plant variety is subject to federal protection only under the PVPA. 7 U.S.C. § 2402(a). The Court should so hold, and declare each of the patents-in-suit invalid.

Respectfully submitted,

BRUCE E. JOHNSON
(Counsel of Record)
S. P. DEVOLDER
LEWIS, WEBSTER, JOHNSON, VAN WINKLE & DEVOLDER, L.L.P.
418 Sixth Avenue
Liberty Building, Suite 620
Des Moines, Iowa 50309-2407
Telephone (515) 243-1000
Facsimile (515) 288-7000
Attorneys for Petitioners